EXPEDITED PROCEDURE EXAMINING GROUP: 3734

Docket: 6971.02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE			
First Named Inventor:	Leonard S. Schultz		
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Title:	**Device and Method for Body Lumen Occlusion**	Group Art Unit:	3734

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF

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(i) REAL PARTY IN INTEREST

The present application has been assigned to Imasurg, Inc., a Minnesota corporation.

(ii) RELATED APPEALS AND INTERFERENCES

None.

(iii) STATUS OF CLAIMS

Claims 29-38 are pending and are herein appealed.

Claims 29-32, 34, 35, and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zdeblick et al. (U.S. Pat. 5,984,967) in view of Conston et al. (U.S. Pat. 5,456,693).

Claims 33, 36, and 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zdeblick et al. and Conston et al. as applied to Claims 29 and 34, and further in view of Wallace et al. (U.S. Pat. 6,585,754).

(iv) STATUS OF AMENDMENTS

No claim amendments were filed subsequent to the final rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to lumen occlusion devices and a method of occluding a body lumen. The lumen occlusion devices (Claims 29 and 38) comprise a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen; a delivery instrument for moving the plug to a selected location in the lumen; and a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen. The method (Claim 34) comprises providing a device comprising a plugging means adapted for substantially completely occluding flow through the body lumen and a delivery means, wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen; inserting the device into the lumen; advancing the device through the lumen to a target site; injecting the biphasic material into the delivery means and conveying the biphasic material to the plugging means; moving the biphasic material through the openings of the plugging means to fix the plugging means relative to the interior wall of the lumen; detaching the delivery means from the plugging means; and withdrawing the delivery means from the lumen, leaving the plugging means inside the lumen.

Independent Claims 29, 34, and 38 are supported by the accompanying specification as follows:

Claim 29 recites: "a plug defining a plurality of openings, the plug being configured and dimensioned to substantially completely occlude flow through the lumen," (*see, e.g.*, pages 13, carryover paragraph; Fig. 4) "a delivery instrument detachably coupled to the plug for moving the plug to a selected location in the lumen," (*see, e.g.*, page 11, carryover paragraph through page 12, second full paragraph; Figs. 2-4) "and a biological bonding agent for being moved through the openings," (*see, e.g.*, page 13, carryover paragraph; page 2 of Preliminary Amendment) "wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen" (*see, e.g.*, page 13, carryover paragraph).

Claim 34 recites: "providing a device comprising a plugging means adapted for substantially completely occluding flow through the body lumen" (*see, e.g.*, page 5, second full paragraph through page 5, carryover paragraph; page 13, carryover paragraph) "and a delivery means" (*see, e.g.*, page 6, first full paragraph; page 11, carryover paragraph) "wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen" (*see, e.g.*, page 13, carryover paragraph) "and the delivery means is detachably coupled to the plugging means;" (*see, e.g.*, page 6, first full paragraph) "inserting said device into the body lumen with the plugging means entering the lumen first;" (*see, e.g.*, page 12, second full paragraph) "advancing said device through said body lumen to a target site;" (*see, e.g.*, page 12, second full paragraph) "injecting the biphasic material into the delivery means and conveying the biphasic material to the plugging means;" (*see, e.g.*, page 7, second full paragraph; page 13, carryover paragraph) "moving said biphasic material through the openings of said plugging means to fix said plugging means relative to the interior wall of said body lumen;" (*see, e.g.*, page 7, second full paragraph; page 13, carryover paragraph) "detaching the delivery means from said plugging means;" (*see, e.g.*, page 7, second full paragraph; page 13, carryover paragraph) "and withdrawing said delivery means from said body lumen, leaving said plugging means inside body lumen" (*see, e.g.*, page 7, second full paragraph; page 13, carryover paragraph).

Claim 38 recites: "a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen," (*see, e.g.*, pages 13, carryover paragraph; Fig. 4) "a delivery instrument detachably coupled to the plug for moving the plug to a selected location in the lumen," (*see, e.g.*, page 11, carryover paragraph through page 12, second full paragraph; Figs. 2-4) "and a biological bonding agent for being moved through the openings," (*see, e.g.*, page 13, carryover paragraph; page 2 of Preliminary Amendment) "wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen" (*see, e.g.*, page 13, carryover paragraph).

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 29-32, 34, 35, and 38 are unpatentable under 35 U.S.C. § 103(a) over Zdeblick et al. (U.S. Pat. 5,984,967) in view of Conston et al. (U.S. Pat. 5,456,693).

Whether Claims 33, 36, and 37 are unpatentable under 35 U.S.C. § 103(a) over Zdeblick et al. and Conston et al. as applied to Claims 29 and 34, and further in view of Wallace et al. (U.S. Pat. 6,585,754).

(vii) ARGUMENT

(A) PRELIMINARY STATEMENT

Appellant respectfully submits that the Examiner has not established a *prima facie* case of obviousness as to Claims 29-38.

First, Zdeblick et al. is non-analogous art because, with respect to Appellant's claimed invention, the functions of the elements are different, the particular fields of endeavor of the disclosed devices as a whole are different, and the problems in the fields of endeavor are different. Second, even accepting for the sake of argument that Zdeblick et al. is analogous art, the asserted combination of two cited references, Zdeblick et al. and Conston et al. is improper because Zdeblick et al. do not disclose a lumen nor can the device disclosed in Zdeblick et al. be modified to expand. Similarly, the device disclosed in Zdeblick et al. is not suitable for lumen occlusion.

Next, even if deemed proper, the combination of references relied on by the Examiner does not teach or suggest all the claim limitations as required under 35 U.S.C. §103(a). As discussed in detail below, none of the references teach or suggest the recited features of Claims 29-38.

Accordingly, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of Claims 29-38.

(B) DESCRIPTION OF THE APPLIED ART

Claims 29-38 stand rejected under 35 U.S.C. § 103 (a). Claims 29-32, 34, 35, and 38 stand rejected over Zdeblick et al. in view of Conston et al., and Claims 33, 36, and 37 stand rejected over Zdeblick et al. and Conston et al., and further in view of Wallace et al.

(1) Zdeblick et al.

Zdeblick et al. disclose an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick et al., Col. 1, ll. 12-14. The device includes an elongated body, tapered along substantially its entire length, defining a hollow interior and having an outer diameter greater than the size of the space between the adjacent vertebrae. Zdeblick et al., Col. 3, ll. 26-30. The body includes an outer surface with opposite

tapered cylindrical portions and a pair of opposite flat tapered side surfaces between the cylindrical portions. Zdeblick et al., Col. 3, ll. 30-33. Thus, at an end view, the fusion device gives the appearance of a cylindrical body in which the sides of the body have been truncated along a chord of the body's outer diameter. Zdeblick et al., Col. 3, ll. 33-36. The cylindrical portions are threaded for controlled insertion and engagement into the end plates of the adjacent vertebrae. Zdeblick et al., Col. 3, ll. 36-38. In a further aspect of the invention, the outer surface is also provided with a number of vascularization openings defined in the flat side surfaces, and a pair of elongated opposite bone ingrowth slots defined in the cylindrical portions. Zdeblick et al., Col. 3, ll. 42-45. The hollow device is provided with an osteogenic material to optimize fusion. Zdeblick et al., Col. 3, ll. 59-61.

(2) Conston et al.

Conston et al. disclose an embolization plug for blood vessels that is compressed so as to be longitudinally insertable into a tubular biological vessel, such as a blood vessel. Conston et al., Abstract. The plug then expands radially inside the vessel by absorbing fluid such as the blood and thereby providing mechanical fixation in, and occlusion of, the vessel. Conston et al., Abstract.

(3) Wallace et al.

Wallace et al. disclose novel structures and novel methods of manufacturing absorbable vaso-occlusive members. Wallace et al., Col. 4, ll. 46-48. The term "absorbable" refers to any agent which, over time, is no longer identifiable at the site of application in the form it was injected, for example having been removed via degradation, metabolism, dissolving or any passive or active removal procedure. Wallace et al., Col. 4, ll. 29-33. In certain embodiments, not all of the material is absorbable, so the term includes both complete and substantially complete absorption over a period of time ranging from hours to months. Wallace et al., Col. 4, ll. 33-37.

(C) REJECTION OF CLAIMS 29-32, 34, 35, AND 38 UNDER 35 U.S.C. § 103(a) OVER ZDEBLICK ET AL. IN VIEW OF CONSTON ET AL.

(1) Zdeblick et al. is Non-analogous Art

Appellant initially submits that relying on Zdeblick et al. as a reference for a 35 U.S.C. § 103 rejection is improper. To rely on a reference under 35 U.S.C. 103, it must be analogous prior art. MPEP 2141.01(a). MPEP 2141.01(a)(iv) discusses analogy in mechanical arts. While a broad spectrum of prior art may be explored, there must be, at least, a similarity of problems between the arts:

> In a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist. MPEP 2141.01(a)(iv), quoting *Stevenson v. International trade Comm.*, 612 F.2d 546, 550 (CCPA 1979) (emphasis added).

Zdeblick et al. disclose an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc (Zdeblick et al., Col. 1, ll. 12-14), and one skilled in the art of lumen occlusion would not look to the art of implants to be placed into the intervertebral space left after the removal of a damaged spinal disc. Specifically, the functions of the elements are different, the particular fields of endeavor of the disclosed devices as a whole are different, and the problems in the fields of endeavor are different.

I. The Functions of the Elements are Different

The function of the lumen occlusion device as claimed and the function of the osteogenic fusion device of Zdeblick et al. are different. Specifically, as claimed, a lumen occlusion device is provided to "occlude flow through the lumen." In contrast, the fusion device of Zdeblick et al. is "configured to restore the normal angular relation between adjacent vertebrae." Zdeblick et al., Col. 3, ll. 24-25. Zdeblick et al. disclose:

> [T]he device 10 has an anterior end 12 and a posterior end 13, which correspond to the anatomic position of the device 10 when implanted in the intradiscal space. The conical body 11 defines a hollow interior 15 which is bounded by a body wall 16 and closed at the posterior end 13 by an end wall 17 (see FIG. 3). The hollow

> interior 15 of the device 10 is configured to receive autograft bone or a bone substitute material adapted to promote a solid fusion between adjacent vertebrae and across the intradiscal space. Zdeblick et al., Col. 5, ll. 8-17.

The function of the claimed lumen occlusion device is to occlude flow through the lumen. The function of the Zdeblick et al. fusion device is to restore the normal angular relation between adjacent vertebrae and promote a solid fusion between adjacent vertebrae and across the intradiscal space. Zdeblick et al. do not disclose a lumen that requires occlusion, but rather discloses the promotion of bone ingrowth. These are unrelated functions.

II. The Fields of Endeavor are Different

The fields of endeavor of the disclosed devices are different. Specifically, Claims 29, 34, and 38 relate to a lumen occlusion device or a method of occluding a lumen. Zdeblick et al. relates to an artificial implant to be placed into the intervertebral space and does not relate to lumen occlusion.

III. The Problems in the Fields of Endeavor are Different

As discussed in the present application:

> The technical problems of dissecting the gallbladder from the liver include stone spillage with puncture site infection, [and] liver bed bleeding . . .
>
> Whichever the technique used, the surgeon must dissect the cystic artery and duct and occlude them with metal clips or ligature before removal of the gallbladder. The cystic duct clip or ligature prevents spillage of bile from the gallbladder and its leakage from the liver. Bile leakage from the cystic duct is one of the most common problems following the cholecystectomy. The leakage could be due to incomplete duct occlusion or dislodgement of a loosely placed clip or ligature from the cystic duct stump. Further, the clip may migrate into the common bile duct, where it can induce cholesterol stones, resulting in severe abdominal and back pain. Specification, Paras. [0007]-[0008].

As previously noted, Zdeblick et al. relates to an implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick et al. do not provide a solution for incomplete duct occlusion or dislodgement of a loosely placed clip or

ligature resulting in leakage from the duct or lumen. Specifically, the fusion device 10 of Zdeblick et al. includes a pair of vascularization openings 24 and 25 defined through each of the truncated side walls 22. Zdeblick et al., Col. 5, ll. 57-59. These openings are intended to provide a passageway for vascularization to occur between the bone implant material within the hollow interior 15 and the surrounding tissue. Zdeblick et al., Col. 5, ll. 62-65. The conical body 11 also defines opposite bone ingrowth slots 27, each of which are oriented at 90° to the truncated side walls 22. Zdeblick et al., Col. 6, ll. 5-7. The bone ingrowth slots 27 are configured to provide maximum opening for bone ingrowth, in order to ensure complete arthrodesis and a solid fusion. Zdeblick et al., Col. 6, ll. 13-16. That is, Zdeblick et al. disclose a solution for the promotion of bone ingrowth and fusion. Zdeblick et al. do not disclose a solution for duct occlusion.

(2) Zdeblick et al. is Not Properly Combinable With Conston et al.

Assuming *arguendo* that Zdeblick et al. is analogous art, Applicant asserts that Zdeblick et al. is not properly combinable with Conston et al. nor any other reference relating to lumen occlusion.

I. Zdeblick et al. Do Not Disclose a Lumen

Zdeblick et al. simply do not disclose a body lumen. Particularly, Zdeblick et al. do not disclose a body lumen as defined in Appellant's specification.

The Examiner previously held a telephone interview with Appellant's representative on September 6, 2007. During the interview, the Examiner asserted that Zdeblick et al. disclose a lumen, in that the space between vertebrae, as illustrated in Figures 6, 7, and 13(a)-(d), is a lumen. Appellant emphatically asserts that the space between vertebrae is not a lumen as is recognized by one skilled in the art, and the Examiner has not provided any evidence to the contrary. Therefore, Zdeblick et al. do not disclose a lumen occlusion device. Specifically, Zdeblick et al. do not disclose a plug or plugging means being configured and dimensioned to occlude flow through a lumen.

The Examiner further asserted that the dictionary definition of a lumen is broad enough to read on the space between vertebrae. While Appellant traverses the Examiner's contortion of the medical term "lumen," the Examiner's use of the dictionary definition is erroneous since in

paragraph [0027] of Appellant's specification, Appellant has clearly and specifically defined the term "lumen:"

> As used herein, "lumen" is defined as the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct. (Emphasis added).

Section 2173.01 of the MPEP states:

> A fundamental principle contained in 35 U.S.C. § 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification.

Section 2111.01(IV) reinforces the concept:

> Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (emphasis added).

Zdeblick et al. disclose an implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. The intervertebral space is not a lumen as recognized by those skilled in the art, nor is the intervertebral space a lumen as that term is defined in Appellant's specification. The Examiner has not provided any appropriate evidence illustrating the manner in which the space between vertebrae fits with Appellant's definition of a lumen, i.e., "the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct." (Emphasis added).

II. Zdeblick et al. Cannot Be Modified to Expand

The osteogenic fusion device of Zdeblick et al. cannot be modified using the teachings of Conston et al. without destroying the function and purpose of the Zdeblick et al. device. As stated above, Zdeblick et al. disclose an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick et al., Col. 1, ll. 12-14. The body of the fusion device "can be made of a medical grade stainless steel or titanium, or other suitable material having adequate strength characteristics set forth herein." Zdeblick et al., Col. 5, ll. 2-5

(emphasis added). The fusion device requires strength to maintain stability of the disc interspace between adjacent vertebrae. Zdeblick et al., Col. 1, ll. 49-52. Zdeblick et al. further point out that one difficulty with available fusion devices is that the devices are not structurally strong enough to support the heavy loads and bending moments applied at the most frequently fused vertebral levels. Zdeblick et al., Col. 2, ll. 37-47. Without such strength and stability, damage to the nerves extending along the spinal column may result. *See, e.g.*, Zdeblick et al., Col. 1, ll. 29-32. Zdeblick et al. further provide several reasons that a preferred fusion device should mimic bone and have a modulus of elasticity that approximates that of human bone. Zdeblick et al., Col. 8, ll. 11-60.

In contrast, Conston et al. disclose an embolization plug for blood vessels that is compressed so as to be longitudinally insertable into a tubular biological vessel, such as a blood vessel. Conston et al., Abstract. The plug then expands radially inside the vessel by absorbing fluid such as the blood and thereby providing mechanical fixation in, and occlusion of, the vessel. Conston et al., Abstract. Conston et al. provide further details of the expansion:

> Typically, the plugs are compressed sufficiently so that their diameter is smaller than the lumen for ease of insertion . . . A dry, highly compressed collagen plug like this fully hydrates and expands to several times its compressed size within a short period of time upon contact with bodily fluid, thereby tightly affixing itself to a particular location within a blood vessel. Conston et al., Col. 2, l. 66-Col. 3, l. 9 (emphasis added).

Combining Conston et al. with Zdeblick et al. would produce an osteogenic fusion device for implanting into the intervertebral space that would expand to several times its compressed size. A fusion device that expands to several times its compressed size would be contrary to the purpose of the Zdeblick et al. fusion device, which is to maintain stability of the disc interspace between adjacent vertebrae. Therefore, Conston et al. teach away from a combination with Zdeblick et al. to provide a suitable osteogenic fusion device. Furthermore, because Conston et al. teach expansion within the blood vessels, there is no reasonable expectation of success in modifying the device of Zdeblick et al. with the teachings of Conston et al.

In the Office Action dated November 28, 2007, the Examiner noted that Zdeblick et al. do not disclose a plug being configured and dimensioned to substantially completely occlude flow through a lumen. Page 3, first full paragraph. However, the Examiner asserted:

> Conston teaches a plug being configured and dimensioned to substantially completely occlude flow through a lumen. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the fusion device of Zdeblick (wherein "fusion" may be considered a form of occlusion) by configuring and dimensioning the plug to substantially completely occlude flow through a body lumen, such as a vessel, as taught by Conston. Office Action dated November 28, 2007, page 3, second full paragraph (emphasis removed).

In the Advisory Action dated February 22, 2008, the Examiner further asserted that Zdeblick et al. "does deal with a similar problem since it is also considered a 'fusion device' for bone, which may be a form of occlusion of tissue."

Appellant initially points out the Examiner's erroneous assertion that "fusion" is synonymous with "occlusion." The Merriam-Webster online dictionary defines "fusion," in the most relevant definition, as "a merging of diverse elements into a unified whole." More particularly, the Merriam-Webster online dictionary defines "spinal fusion," for which the Zdeblick et al. device is used, as "surgical fusion of two or more vertebrae for remedial immobilization of the spine." Neither definition relates to occluding flow through a lumen.

Furthermore, in response to Appellant's remarks that the fusion device disclosed by Zdeblick et al. cannot be modified to expand, the Examiner asserted:

> [T]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Advisory Action dated February 22, 2008.

It appears the Examiner has misunderstood Appellant's remarks. According to the MPEP § 2141.02(VI), "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). As stated above, the plug disclosed by Conston et al. expands radially inside the vessel by absorbing fluid such as the blood and thereby providing mechanical fixation in, and occlusion of, the vessel. Conston et al., Abstract. Indeed, Conston et al. disclose that the plug "expands to several times its compressed size within a short period of time upon contact with bodily fluid." Conston et al.,

Col. 3, ll. 5-9 (emphasis added). That is, Conston et al. disclose occlusion only by expansion of the plug. *See, e.g.*, Conston et al., independent Claims 1 and 21 ("being capable of expanding radially inside said vessel by absorbing fluid and thereby providing mechanical fixation in and occlusion of said vessel").

As also stated above, the fusion device of Zdeblick et al. requires strength to maintain stability of the disc interspace between adjacent vertebrae. Zdeblick et al., Col. 1, ll. 49-52. Zdeblick et al. further point out that one difficulty with available fusion devices is that the devices are not structurally strong enough to support the heavy loads and bending moments applied at the most frequently fused vertebral levels. Zdeblick et al., Col. 2, ll. 37-47. According to the MPEP § 2141.02(VI), it is improper to combine the teachings of Zdeblick with the teachings of Conston et al. without considering the teachings of Conston et al. as a whole. Since Conston et al. disclose occlusion only by expansion of the plug, combining the teachings of Conston et al. would require that the fusion device of Zdeblick et al. expand to several times its size in order to cause occlusion. A fusion device that expands to several times its compressed size would be contrary to the purpose of the Zdeblick et al. fusion device, which is to maintain stability of the disc interspace between adjacent vertebrae. Therefore, Conston et al. teach away from a combination with Zdeblick et al. to provide a suitable osteogenic fusion device. Furthermore, because Conston et al. teach occlusion by expansion, there is no reasonable expectation of success in modifying the device of Zdeblick et al. with the teachings of Conston et al.

The PTO has the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. MPEP § 2142 ("The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness."). "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (citations omitted). More recently, the U.S. Supreme Court indicated:

> When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. . . . . a

> patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct 1727, 1741 (2007).

Therefore, the PTO should show at least that some objective teaching or suggestion in the prior art or knowledge generally held by one of ordinary skill that would lead an individual to modify the relevant teachings of a reference *or* should identify a reason that would have prompted a person of skill in the field to combine the elements in the way claimed. *Id.* For present purposes, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The PTO should provide "an apparent reason to combine the known elements in the fashion claimed" and "this analysis should be made explicit." *KSR Int'l Co.*, 127 S.Ct. at 1741.

The Examiner has provided no more than conclusory statements that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to modify the fusion device of Zdeblick . . . by configuring and dimensioning the plug to substantially completely occlude flow through a body lumen, such as a vessel, as taught by Conston, since it was well known in the art to effectively block body lumens, particularly blood vessels, for a variety of situations such as controlling bleeding in the brain or renal embolization, and also using embolization plugs that also may deliver agents to the lumen." Office Action dated November 28, 2007, page 3, second full paragraph. Indeed, the Examiner has not provided any evidence that it would be obvious to one of ordinary skill in the art of spinal fusion to modify a fusion device with the teachings found in the art of lumen occlusion. See, *KSR Int'l Co.*, 127 S.Ct. at 1741 (stating "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does"). Moreover, it makes no sense to assume that, presented with a patent for a spinal fusion device and another patent teaching occlusion by expansion of an embolization plug, one of ordinary skill in the art would find it obvious to combine the two references to achieve the claimed invention. Therefore, the asserted combination cannot be sustained under the standard

articulated in *KSR*, and the combination of Zdeblick et al. and Conston et al. is improper and insufficient to establish obviousness absent some support or reason to combine the elements in the way claimed.

(3) Zdeblick et al. is Not Suitable for Lumen Occlusion

Zdeblick et al. do not disclose a device that is suitable, or adaptable, for lumen occlusion. The device disclosed in Zdeblick et al. is a threaded device configured to be screw threaded into the end plates of adjacent vertebrae. Zdeblick et al., Col. 5, ll. 18-20. Furthermore, the device includes parallel truncated side walls that are preferably flat to facilitate insertion of the fusion device between the end plates of the adjacent vertebrae and provide an area between for bony fusion. Zdeblick et al., Col. 5, ll. 39-43. With truncated side walls, the device gives the appearance, at its end view, of an incomplete circle. Zdeblick et al., Col. 5, ll. 45-47. Because of these characteristics, the fusion device disclosed in Zdeblick et al. is not conducive to lumen occlusion, particularly lumen occlusion of a lumen as defined by Appellant as "the space or cavity in the interior of a tubular structure or organ, such as an artery, vein, tube or duct, such as the bile duct." Particularly, threaded fusion devices would be improper for lumen occlusion as the threads would impede movement through the lumen to the location of occlusion. Similarly, truncated side walls leave openings between the fusion device and the interior wall of the lumen, where occlusion would be precluded. Therefore, there is no reasonable expectation of success in modifying the device of Zdeblick et al. with the teachings of Conston et al., and the combination of Zdeblick et al. with the teachings of Conston et al. would not be capable of performing the intended use of the claimed invention.

In the Advisory Action dated February 22, 2008, the Examiner stated:

> Although the examiner cited the hollow embodiment of Zdeblick (Figure 2), which may not necessarily be considered as a device that would "substantially completely occlude flow through the lumen," Zdeblick also suggests a solid embodiment (col. 3, lines 63-67) that may more thoroughly occlude flow if placed in a body lumen.

Nonetheless, Zdeblick et al. discloses that the solid embodiment continues to have threads and truncated side walls:

> In a further embodiment using a porous material, the interbody fusion device 110 of FIG. 8A retains the tapered configuration of

> the previous embodiments, but is solid instead of hollow. The device 110 comprises a tapered body 111 having a larger outer diameter at is (sic) anterior end 112 than at is (sic) posterior end 113. The entire body 111 is solid leaving a closed surface, such as surface 115, at both ends of the implant. The device includes the interrupted threads 118, starter threads 119, and truncated side walls 122 of the prior embodiments. Zdeblick et al., Col. 7, l. 62 – Col. 8, l. 4 (emphasis added).

While Zdeblick et al. disclose that the starter threads may be eliminated (Zdeblick et al. Col. 8, ll. 5-7), the interrupted threads and truncated side walls are retained. Thus, even with a solid embodiment, there is no reasonable expectation of success in modifying the device of Zdeblick et al. with the teachings of Conston et al., and the combination of Zdeblick et al. with the teachings of Conston et al. would not be capable of performing the intended use of the claimed invention.

In the Interview Summary dated May 6, 2008, the Examiner further posited that "Zdeblick was a complete occluder given that it has an end wall 17 (Figure 10) that would serve as a complete barrier to flow." For the same reasons provided above, i.e., interrupted threads and truncated side walls, even with an end wall, there is no reasonable expectation of success in modifying the device of Zdeblick et al. with the teachings of Conston et al., and the combination of Zdeblick et al. with the teachings of Conston et al. would not be capable of performing the intended use of the claimed invention.

(4) Neither Zdeblick et al. nor Conston et al. Disclose the Invention as Claimed in Claims 29-32

Assuming *arguendo* the combination of Zdeblick et al. and Conston et al. is proper, the combination does not teach or suggest the present invention as claimed in Claims 29-32. Independent Claim 29, for example, includes the following distinct features: a plug defining a plurality of openings, the plug being configured and dimensioned to substantially completely occlude flow through the lumen . . . and a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen. For the reasons set forth below, the recited features are not disclosed, taught, or suggested in the combination of Zdeblick et al. and Conston et al.

Zdeblick et al. do not teach or suggest occluding flow through a body lumen, and particularly do not teach or suggest substantially completely occluding flow through a body lumen. Rather, Zdeblick et al. disclose an osteogenic fusion device for implantation into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick et al., Col. 1, ll. 12-14. The fusion device comprises vascularization openings for providing a passageway for vascularization to occur between the implant material within the interior of the device and the surrounding tissue. Zdeblick et al., Col. 5, ll. 59-65. However, the fusion device disclosed in Zdeblick et al. does not occlude the flow through a body lumen. Particularly, the fusion device disclosed in Zdeblick et al. does not substantially completely occlude flow.

Furthermore, Zdeblick et al. do not teach or suggest "a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen." Rather, contrary to any assertion by the Examiner, Zdeblick et al. disclose that during a surgical implantation procedure, the surgeon may apply an osteogenic material to a fusion device by packing the hollow interior with an osteogenic material. Zdeblick et al., Col. 8, ll. 61-64. Alternatively, the osteogenic material can be applied by introducing an osteogenic composition to the pores of the bone ingrowth material. Zdeblick et al. Col. 8, ll. 64-67. Zdeblick et al. disclose, in one embodiment, the composition includes a bone morphogenic protein (BMP) in a liquid carrier which can be introduced into the pores to promote fusion. Zdeblick et al., Col. 10, ll. 17-20. In some cases, a BMP-bonding agent is applied to the porous biocompatible material of the implant prior to introduction of the BMP so that the agent can coat the pores of the device. Zdeblick et al., Col. 10, ll. 53-56. Neither of these teachings in Zdeblick et al. relate to extruding a biological bonding agent, as required in Appellant's Claim 29. Rather, the osteogenic compositions are applied to the fusion device of Zdeblick et al. prior to implantation of the device and do not require extrusion through a plurality of openings to an interior wall of a lumen for binding a plug to the interior of the lumen.

Conston et al. fail to remedy the disclosure deficiencies of Zdeblick et al. Conston et al. also do not disclose a biological bonding agent. In one embodiment, Conston et al. disclose an aggressive method of compromising the lumen in the space between two plug pieces by introduction of surface active agents or alcohols into a spacer capsule disposed between the two plug pieces. Conston et al., Col. 4, ll. 14-16. An alcohol may serve as a dehydrating agent,

while a surface agent will effectively destroy the epithelial layer. Conston et al., Col. 4, ll. 16-20. Nowhere, however, do Conston et al. disclose a biological bonding agent for being moved through openings of a plug.

In view of the above remarks, the combination of Zdeblick et al. and Conston et al. do not teach or suggest the recitations of at least independent Claim 29. Claims 30-32 depend from Claim 29 and are patentable for at least the same reasons as Claim 29 and for the additional limitations recited therein. Accordingly, withdrawal of the rejection and allowance of the pending claims are requested.

(5) Neither Zdeblick et al. nor Conston et al. Disclose the Invention as Claimed in Claims 34 and 35

Independent Claim 34, for example, includes the following distinct features: a plugging means adapted for substantially completely occluding flow through the body lumen . . . wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen . . . [and] injecting the biphasic material into the delivery means and conveying the biphasic material to the plugging means. For the reasons set forth above with respect to independent Claim 29, the recited features are not disclosed, taught, or suggested in the combination of Zdeblick et al. and Conston et al.

Additionally, neither Zdeblick et al. nor Conston et al., alone or in combination, disclose, teach, or suggest "injecting the biphasic material into the delivery means and conveying the biphasic material to the plugging means." The Examiner has, furthermore, not provided any evidence, other than mere conclusory statements, that any of the cited references disclose such limitations.

In view of the above remarks, the combination of Zdeblick et al. and Conston et al. do not teach or suggest the recitations of at least independent Claim 34. Claim 35 depends from Claim 34 and is patentable for at least the same reasons as Claim 34 and for the additional limitations recited therein. Accordingly, withdrawal of the rejection and allowance of the pending claims are requested.

(6) Neither Zdeblick et al. nor Conston et al. Disclose the Invention as Claimed in Claim 38

Independent Claim 38 includes the following distinct features: a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen . . . and a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen. For the reasons set forth above with respect to independent Claim 29, the recited features are not disclosed, taught, or suggested in the combination of Zdeblick et al. and Conston et al.

Furthermore, the Merriam-Webster online dictionary defines "occlude," in the most relevant definition, as "to close up or block off." The Examiner, however, in the Advisory Action dated February 22, 2008 and Interview Summary dated May 6, 2008, contends that Conston et al. teach varying degrees of occlusion, depending on the application, and points to column 1, line 62 through column 2, line 5 for support. However, contrary to the Examiner's assertion, Conston et al. do not teach varying degrees of occlusion. Rather, Conston et al. only disclose permanent or temporary occlusion:

> In certain applications, it may be desirable that the plug material can occlude a flow permanently, and be replaced by native tissue. In other applications such as chemoembolization of the hepatic artery, on the other hand, temporary occlusion may be preferred, allowing the material to erode gradually and normal flow restored in the vessel. Conston et al., Col. 1, l. 64 – Col. 2, l. 3.

That is, the vessel can be occluded permanently, or the vessel can be occluded temporarily until the plug material begins to erode. Nowhere do Conston et al. disclose varying degrees of occlusion.

In view of the above remarks, the combination of Zdeblick et al. and Conston et al. do not teach or suggest the recitations of independent Claim 38. Accordingly, withdrawal of the rejection and allowance of the pending claims are requested.

(D) REJECTION OF CLAIM 33, 36, AND 37 UNDER 35 U.S.C. § 103(a) OVER ZDEBLICK ET AL. AND CONSTON ET AL., AND FURTHER IN VIEW WALLACE ET AL.

Claim 33 depends from Claim 29 and Claims 36 and 37 depend from Claim 34, and each are patentable for at least the same reasons as Claims 29 and 30, respectively, and for the additional limitations recited therein. Accordingly, withdrawal of the rejection and allowance of the pending claims are requested.

Furthermore, Zdeblick et al. is not properly combinable with Wallace et al. because Wallace et al. teach away from Zdeblick et al. Zdeblick et al. disclose an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Zdeblick et al., Col. 1, ll. 12-14. That is, Zdeblick et al. disclose a permanent, artificial implant. In contrast, Wallace et al. disclose novel structures and novel methods of manufacturing absorbable vaso-occlusive members. Wallace et al., Col. 4, ll. 46-48. The term "absorbable" refers to any agent which, over time, is no longer identifiable at the site of application in the form it was injected, for example having been removed via degradation, metabolism, dissolving or any passive or active removal procedure. Wallace et al., Col. 4, ll. 29-33. In certain embodiments, not all of the material is absorbable, so the term includes both complete and substantially complete absorption over a period of time ranging from hours to months. Wallace et al., Col. 4, ll. 33-37. However, the absorbable vaso-occlusive members are to be contrasted with hybrid devices made up of both absorbable material and non-absorbable material . . . in which less than substantially all of the device is absorbed over time. Therefore, Wallace et al. teach away from permanent fusion devices, and there is no reasonable expectation of success in modifying the device of Zdeblick et al. with the teachings of Wallace et al.

(E) CONCLUSION

For the reasons set forth above, Appellant respectfully requests reversal of the Examiner's rejection of Claims 29-38 under 35 U.S.C. § 103(a).

This response is being submitted on or before June 28, 2008, with the required fee of $255.00, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

Date: June 11, 2008

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(viii) CLAIMS APPENDIX

I claim:

1-28. (Canceled)

29. A lumen occlusion device, said device comprising:

a plug defining a plurality of openings, the plug being configured and dimensioned to substantially completely occlude flow through the lumen;

a delivery instrument detachably coupled to the plug for moving the plug to a selected location in the lumen; and

a biological bonding agent for being moved through the openings;

wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen.

30. The lumen occlusion device of claim 29, wherein the bonding agent comprises a biphasic material.

31. The lumen occlusion device of claim 29, wherein the bonding agent comprises a biosorbable material.

32. The lumen occlusion device of claim 30, wherein the biphasic material is biosorbable.

33. The lumen occlusion device of claim 29, wherein the bonding agent is a shape memory material.

34. A method of occluding a body lumen, the method comprising the steps of:

providing a device comprising a plugging means adapted for substantially completely occluding flow through the body lumen and a delivery means, wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen and the delivery means is detachably coupled to the plugging means;

inserting said device into the body lumen with the plugging means entering the lumen first;

advancing said device through said body lumen to a target site;

injecting the biphasic material into the delivery means and conveying the biphasic material to the plugging means;

moving said biphasic material through the openings of said plugging means to fix said plugging means relative to the interior wall of said body lumen;

detaching the delivery means from said plugging means; and

withdrawing said delivery means from said body lumen, leaving said plugging means inside said body lumen.

35. The method of claim 34, wherein the biphasic material comprises a biosorbable material.

36. The method of claim 34, wherein the biphasic material is a shape memory material.

37. The method of claim 36, wherein the biphasic material is biosorbable.

38. A lumen occlusion device, said device comprising:

a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen;

a delivery instrument detachably coupled to the plug for moving the plug to a selected location in the lumen; and

a biological bonding agent for being moved through the openings;

wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen.

(ix) EVIDENCE APPENDIX

None.

(x) RELATED PROCEEDINGS APPENDIX

None.